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| 09/534,893 | 03/24/2000 | Joel Lazewatsky | DM6993 | 2336 |

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/27/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/534,893

Applicant(s)

LAZEWATSKY, JOEL

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/24/00; 6/27/00; 1/16/01; and 7/16/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 18, 19, 25 and 33-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 20-24, 26-32 and 55-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 & 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the following:
 - a. the paper filed 3/24/00, wherein the specification was amended; and
 - b. Paper No. 11, filed 1/11/02, wherein claim 6 was amended and claims 20-58 were added.

Note: Claims 1-58 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election of Group IV with traverse is acknowledged. The traversal is on the ground that for Group IV, in Formula IV, AL1 is an aminocarboxylate and AL2 is a trisubstituted phosphine rather than both AL1 and AL2 being trisubstituted phosphines. In addition, Applicant has elected the species of Compound IV on page 25 for prosecution.

First, the Examiner would like to clarify the record. The restriction requirement mailed 6/20/01, Paper No. 9, was vacated and a new restriction requirement mailed on 4/10/02, Paper No. 12 (this is the restriction to which Applicant elected Group IV and the compound on page 25 as stated above).

Secondly, in regards to the traversal, Applicant is correct in the definitions of the variables of AL1 and AL2. Hence, the claims will be examined as such. Therefore, *the restriction requirement is still deemed proper and is made FINAL.*

Note: The full scope of Group IV has been examined. The search has not been extended beyond Group IV. Thus, Applicant is respectfully requested to cancel all non-elected subject matter.

WITHDRAWN CLAIMS

3. Claims 1-16, 18, 19, 25, and 33-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 REJECTIONS

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 17, 20-24, 26-32, and 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, lines 5-6: The claim as written is ambiguous because of the phrase 'physical property'. In particular, it is unclear what properties are being examined in the method of pulmonary embolus. Applicant is respectfully requested to clarify the phrase in order that one may be able to readily ascertain what is being claimed. In regards to claims 20-24, 26-32, and 55-58, the claims are ambiguous because they depend from claim 17 for which the phrase 'physical property' is unclear.

102/103 REJECTIONS

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 17, 20-24, 26-32, and 55-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barrett et al (Bioconjugate Chemistry, 1997, Vol. 8, pages 155-160).

Art Unit: 1616

Barr et al disclose the biological evaluation of thrombus imaging using a water-soluble phosphine as a coligand used in combination with a hydrazinonicotinamide-modified cyclic glycoprotein IIb/IIIa receptor antagonist labeled with Tc-99m(see entire document, especially, abstract). In particular, the antagonist [cyclo(D-Val-NMeArg-Gly-Asp-Mamb(5-(6-(6-hydrazinonicotinamido)hexanamide)))] was labeled with Tc-99m using tricine and a water soluble phosphine, TPPTS (trisodium triphenylphosphine-3,3',3''-trisulfonate, see Figure 1, page 156). The thrombosis imaging agents were incorporated into the arterial and venous portions of the thrombus and a gamma camera scintigraphy was used to allow visualization of the thrombosis (see Figure 6, page 159). Thus, both Applicant and Barrett disclose a method of imaging a pulmonary embolic wherein Applicant's Compound IV is utilized. Furthermore, on pages 159-160, bridging paragraph, it is disclosed that the unfiltered images of the complexes in the DVT imaging model as set forth in Figure 6, comprise a scale which represents a fixed scale that increases to the most dense pixel. The region of interest is data acquired from the DVT images comparing the images to the target and the background.

Alternatively, if the reference does not anticipate the instantly claimed invention, then, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to following the suggestions of Barrett et al and generate method steps as set forth by Applicant because a skilled practitioner in the art would realize that administering the compound and allowing it to reach the target area is the same as Applicant's step a wherein the radiolabeled compound localizes at the pulmonary

embolus and steps b – e are a result of the apparatus scanning the desired area and generating images of the subject (e.g., using gamma camera scintigraphy to visualize the target).

9. Claims 17, 20-24, 26-32, and 55-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Sworin et al (US Patent No. 5,750,088).

Sworin et al disclose the preparation of radiopharmaceuticals useful as imaging agents for the diagnosis of cardiovascular disorders. The imaging agents comprise a stable hydrazone modified biologically active molecule that interacts with gamma emitting radioisotopes to form radiopharmaceuticals that selectively localize at sites of disease and are visualized using gamma scintigraphy (see entire document, especially, abstract; column 26, lines 12-14). In columns 37-38, lines 20-35, Applicant's Compound IV as set forth on page 25 is disclosed. One aspect of the instant invention contemplates a method of imaging the site of thrombotic disease in a patient involving the steps of (a) synthesizing the radiopharmaceutical which localizes at the site of the thrombotic disease; (b) administering the radiopharmaceutical to a subject; and (3) imaging the subject using either planar or SPECT gamma scintigraphy.


Alternatively, if the reference does not anticipate the instantly claimed invention, then, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to following the suggestions of Sworin et al and generate method steps as set forth by Applicant because a skilled practitioner in the art would realize that

administering the compound and allowing it to reach the target area is the same as Applicant's step a wherein the radiolabeled compound localizes at the pulmonary embolus and steps b – e are a result of the apparatus scanning the desired area and generating images of the subject (e.g., using gamma camera scintigraphy to visualize the target).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


D. L. Jones
Primary Examiner
Art Unit 1616

September 24, 2002